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10/595,536	02/08/2007	Donald Schomer	2329-00155 TJF	7815
23505	7590	05/12/2008	EXAMINER	
CONLEY ROSE, P.C.			DOUGHERTY, SEAN PATRICK	
David A. Rose				
P. O. BOX 3267			ART UNIT	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/595,536	Applicant(s) SCHOMER ET AL.	
	Examiner SEAN P. DOUGHERTY	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-39 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 29-39 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>02/08/2007, 04/26/2006, 04/26/2006</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

This is the *initial* Office action based on the 10/595536 application filed August 1, 2006. Claims 29-39, as amended, are currently pending and have been considered below. Claim 36 is independent.

Claim Objections

Claims 29-35 objected to because of the following informalities: claim 29-35 are dependent from claim 36, however, are numbered before claim 36 and should be numbered after claim 26; claims 32 and 33 state "the method according to claim 36" and it appears that they should state --the kit according to claim 36--.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 29, 32 and 35-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Reiley et al (US Patent No. 6,575,919).

Regarding claim 29, Reiley discloses the kit according to claim 36, wherein:

said expandable device comprises a volume of contrast medium (filling material [138]; col. 10, lines 13-15; col. 10, lines 31-36).

Regarding claim 32, Reiley discloses the method according to claim 36 (see *claim objection*), wherein:

said expandable device includes a bioactive agent (ProOsteon™, col. 11, line 48).

Regarding claim 35, Reiley discloses the kit according to claim 36, wherein said tool comprises:

a cannulated scalpel (cannula [50]) having a side aperture proximal its distal end (interior lumen [44]; see Fig. 4);

an elongate body housed within said cannulated scalpel and comprising two radially extendable arms (therapeutic element [132]; col. 10, lines 7-12) constructed such that radially extending arms causes them to extend outward through said aperture (see Fig. 13) and retracting said arms causes them to close (see Fig. 12).

Regarding claim 36, Reiley discloses a kit for performing a procedure on a spine, the spine including an epidural space containing a thecal sac, the kit comprising:

as insertion member for accessing the epidural space (second instrument [40]);

an expandable device adapted to be inserted into the epidural space by the insertion member and expanded so as to compress a portion of the thecal sac and

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provide a safety zone within the epidural space (therapeutic element [132]; col. 10, lines 7-12); and

a tool including means for engaging the ligamentum flavum (penetrating surface [35]) and means for resecting a section of the ligamentum flavum (drill bit instrument [70] including cutting edges [76]).

Regarding claim 37, Reiley discloses the kit according to claim 36 wherein said tool comprises:

a cannula (cannula [50]) having a side aperture proximal its distal end (interior lumen [44]; see Fig. 4);

a barbed member coaxially received within said cannula (drill bit instrument [70] including cutting edges [76]); and

a cutting member received on said cannula (penetrating surface [35]).

Regarding claim 38, Reiley discloses the kit according to claim 36 wherein:

said kit further includes means for engaging a first anatomical structure (cannula [50]) and means for affixing said first structure to a second anatomical structure (penetrating surface [35]; drill bit instrument [70] including cutting edges [76]).

Regarding claim 39, Reiley discloses the kid according to claim 36 wherein:

said kit further includes means for engaging and retracting the ligamentum flavum (cannula [50]) and means for anchoring the ligamentum flavum (penetrating surface [35]; drill bit instrument [70] including cutting edges [76]).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Reiley et al (US Patent No. 6,575,919) in view of Bennick, Jr (US Patent No. 4,283,129).

Regarding claim 30, Reiley discloses the kit according to claim 29, including:
a contrast medium as applied to claim 29 above.

Reiley does not appear to disclose the kit according to claim 29, wherein:
the contrast medium comprises a radio-opaque non-ionic myelographic contrast medium.

However, Bennick, a reference in analogous art discloses the kit according to claim 29, where:

the contrast the contrast medium comprises a radio-opaque non-ionic myelographic contrast medium ("inject radio opaque dyes" col. 8, lines 16-17).

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Reiley and Bennick before him or her to modify the contrast medium of Reiley to include radio-opaque non-ionic myelographic properties of Bennick. The motivation for doing so would have been "inject radio opaque dyes into a patient and to observe the dyes through radiological methods for diagnostic purposes" (Bennick: col. 8, lines 16-18).

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Reiley et al (US Patent No. 6,575,919) in view of Edwards et al (US Patent No. 5,985,320).

Regarding claim 31, Reiley disclose the kit according to claim 36, wherein:

said expandable device comprises a volume that is injectable (col. 10, lines 13-36).

Reiley does to appear to disclose the kit according to claim 36, wherein:
said expandable device comprises a volume that is injectable at ambient temperatures and more viscous at body temperature.

However, Edwards, a reference in analogous art discloses the kit according to claim 36, wherein:

said expandable device comprises a volume that is injectable at ambient temperatures and more viscous at body temperature (col. 7, lines 50-57).

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Reiley and Edwards before him or her to modify the injectable volume of Reiley to include viscous formulation of Edwards. The motivation for doing so would have been to “provide compositions and methods for enhancing intracellular delivery of bioactive and/or diagnostic agents. It is a further object of the present invention to provide less invasive methods for delivering high molecular weight and labile drugs, such as proteins and nucleic acid molecules, and diagnostic agents.” (Edwards: col. 2, lines 6-13).

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Reiley et al (US Patent No. 6,575,919) in view of Sharps et al (US Patent No. 6,602,248).

Regarding claim 33, Reiley discloses the method according to claim 36 (see *claim objection*), including:

a contrast medium as applied to claim 29 above.

Reiley does not appear to disclose the kit according to claim 29, wherein:
the contrast medium includes a steroid.

However, Sharp, a reference in analogous art discloses disclose the kit according to claim 29, wherein:

the contrast medium includes a steroid (“epidural steroid injection” col. 55, line 13).

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Reiley and Sharps before him or her to modify the contrast medium of Reiley to include the steroid properties of Sharps. The motivation for doing so would have been “diminish perineural inflammation of an affected nerve root, leading to alleviation of discogenic pain” to provide “significant improved patient care” (Sharps: col. 55, lines 13-25).

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SEAN P. DOUGHERTY whose telephone number is (571)270-5044. The examiner can normally be reached on Monday-Thursday, 7:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. P. D./
Examiner, Art Unit 3736

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/Max Hindenburg/

Supervisory Patent Examiner, Art Unit 3736